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A randomised controlled trial of oxytocin bolus versus oxytocin bolus and infusion for the control of blood loss at elective caesarean section

Submission date 10/12/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/03/2008	**Overall study status** Completed	
Last Edited 21/08/2019	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2006-004799-11

Protocol serial number
EudraCT number 2006-004799-11

Study information

Scientific Title
A multi-centre randomised controlled trial of oxytocin 5 IU bolus and placebo infusion versus oxytocin 5 IU bolus and 40 IU infusion for the control of blood loss at elective caesarean section

Acronym
ECSSIT - Elective Caesarean Section Syntocinon Infusion Trial

Study objectives
The hypothesis is that an oxytocin infusion used in addition to an oxytocin bolus at elective caesarean section will reduce the risk of major haemorrhage and anaemia.

Please note that the pilot study to this trial is assigned to ISRCTN40302163: A randomised controlled trial of oxytocin 5 IU versus oxytocin 5 IU and 30 IU infusion for the control of blood loss at elective caesarean section: a pilot study (see http://www.controlled-trials.com /ISRCTN40302163).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Central Trials Ethics Committee (National Maternity Hospital, Holles Street, Dublin, Ireland) on the 29th November 2007.

Study design
Multi-centre double blinded randomised controlled trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Study of blood loss at caesarean section associated with different use of oxytocin

Interventions
Patients will be randomised in a double-blind trial to receive either:
1. An intravenous slow bolus of oxytocin (5 IU) and placebo infusion (500 ml 0.9% saline), or
2. An intravenous slow bolus of oxytocin (5 IU) and oxytocin infusion (40 IU in 500 ml 0.9% saline over four hours)

At elective caesarean section. The patients will be followed-up until discharge from the hospital post-natally.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Oxytocin

Primary outcome(s)
To compare:
1. The incidence of major obstetric haemorrhage (greater than or equal to 1000 ml)
2. The need for an additional uterotonic agent

We will define major obstetric haemorrhage in two ways:
1. Estimated blood loss as described by theatre staff
2. Estimated blood loss as calculated from pre- and post-operative haematocrit. The post-operative haematocrit will be measured at 48 hours.

Key secondary outcome(s))
To compare:
1. The estimated mean operative blood loss and early lochial loss
2. The objective change in haemoglobin (Hb) and haematocrit before and 48 hours after delivery
3. The incidence of severe anaemia (Hb fall greater than or equal to 20%) 48 hours after delivery
4. The need for blood transfusion and/or blood products
5. The incidence of side effects
6. The post-natal length of stay on the labour ward and in the hospital

The outcomes will be measured at various timepoints - from the time of the operation to discharge from the hospital. Clinical follow-up of the mother will be completed prior to hospital discharge.

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Healthy women
2. Greater than 36 weeks gestation
3. Singleton pregnancies
4. Booked for elective caesarean section

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
2069

Key exclusion criteria
1. Placenta praevia
2. Thrombocytopaenia
3. Coagulopathies
4. Previous major obstetric haemorrhage (greater than 1000 ml)
5. Patients receiving anti-coagulant therapy
6. Non-English speakers
7. Under 18 years of age

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Ireland

Study participating centre
Department of Obstetrics & Gynaecology
Dublin
Ireland
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Sponsor information

Organisation
Health Research Board of Ireland (Ireland)

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Government

Funder Name
Health Research Board of Ireland (Ireland) (ref: RP/2007/171)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2011	21/08/2019	Yes	No
Protocol article	protocol	24/08/2009		Yes	No